

REMARKS

Upon entry of the amendment, claims 5-12, 17, 19-26, and 28-56 will be pending in the application. Claim 56 is newly added. Support for new claim 56 appears in the specification at, e.g., page 6, lines 5-8. No new matter is added.

As an initial matter, Applicants request withdrawal of the finality of the instant Office action. Applicants' previous submission on January 11, 2007 included a Request for Continued examination and an Amendment. The Amendment included claim amendments that change the claimed invention (see, e.g., the amendment to claims 5 and 17 in the January 11, 2007 Amendment). The amendment to claim 5 altered the scope of claim 5 relative to the scope of claim 5 pending prior to the January 11, 2007 amendment. In particular, the amendment to claim 5 submitted on that date required that the claimed pharmaceutical composition comprise a therapeutically effective delayed release oral dosage form of a human interleukin-11 ("IL-11") polypeptide (newly added language underlined). This changed the scope of the claim, as the previous version was not limited to a human IL-11 polypeptide but required only that the polypeptide had the amino acid sequence of a human IL-11 polypeptide. The amendment on January 11, 2007 thus changed the claimed invention.

A final action is not proper in first action when the claims have been amended in the previous response so that they are no longer drawn to the same invention. MPEP § 706.07(b) states (emphasis added):

The claims of a new application may be finally rejected in the first Office action in those situations where (A) the new application is a continuing application of, or a substitute for, an earlier application, and (B) all claims of the new application

(1) **are drawn to the same invention** claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application.

Because Applicants previous response amended the claims, finality if not appropriate in the instant action. Applicants request that the finality of the Action be withdrawn and the fee for requesting continued examination submitted with the instant response be refunded.

Status of Claims

Claims 5-12, 17, 19-26, and 28-55 are currently pending. Claims 42-52 have been withdrawn by the Examiner. It is understood that withdrawn method claims will be rejoined upon allowance of a linking claim. Such rejoinder is respectfully requested.

Applicants respectfully request reconsideration of the pending claims in light of the following remarks.

Reply to Rejection under 35 U.S.C. § 103(a)

Claims 5-12, 17-22, 25 and 28-41 are rejected as obvious in view of Savastano *et al.*, US Patent No. 5,681,584 (“Savastano”) in light of Greenwood-van Meerveld *et al.*, J. Pharmacol. Exp. Ther., Col.; 299(1) 58-66 (2001) (“Greenwood”). Applicants traverse.

Applicants submitted in a previous response a declaration of co-inventor Nicholas Warne showing Greenwood is not available as prior art under 35 U.S.C. § 102(a) because it represents the inventors’ own work. On page 4 of the Office Action, the Examiner finds that the declaration is insufficient to satisfy the question of inventorship with respect to the subject matter disclosed in Greenwood. In reaching this conclusion, the Examiner incorrectly relies on the holding in *In re Katz*, 687 F.2d 450

(CCPA 1982) to read that a statement from the authors of the publication is required to disclaim inventorship. In contrast to this position, however, the court in *Katz* clearly held that a statement by an inventor under oath is sufficient to establish that the subject matter disclosure was his original work, and his alone. See *Katz* at 455. Requiring a statement from the author of the publication is improper:

The board and the examiner held that "disclaiming affidavits or declarations by the other authors are required to support appellant's position that he is, in fact, the sole inventor of the subject matter described in the article and claimed herein." **This was clear error.** Submission of such affidavits or declarations would have ended the inquiry, but we do not agree that they are required by the statute or Rule 132. **What is required is a reasonable showing supporting the basis for the applicant's position.**

Katz at 455 (emphasis added).

The Declaration of co-inventor Nicholas W. Warne submitted in the previous response establishes that he has read the publication in question and asserts that those authors are not inventors of the subject matter claimed in the application (see paragraphs 2 and 3 of the declaration). This showing is sufficient to provide an evidentiary basis for establishing that the subject matter disclosed in Greenwood is the inventors' own work. As such, Greenwood is not prior art against the pending claims. Without the use of Greenwood as prior art, this rejection is moot. Accordingly, Applicants respectfully request withdrawal of this rejection.

Reply to the Obviousness-type Double Patenting Rejection

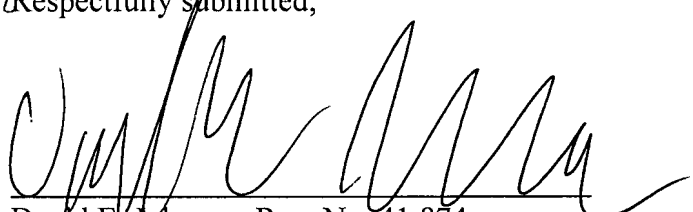
Claims 5, 17-20, 28-31, and 38-39 are provisionally rejected over claim 13 of U.S.S.N. 10/360,906 ("the '906 application"). The '906 application is now abandoned. Thus, this rejection is now moot.

An indication of allowance of all claims is respectfully solicited. A request for continued examination and accompanying fee accompany this submission. Please charge any additional fees due or credit any overpayment of same to the undersigned's Deposit Account No. 50-0311, Reference No. 22058-544.

Respectfully submitted,

Dated: October 31, 2007

By:



David E. Johnson, Reg. No. 41,874
Sheridan K. Snedden, Reg. No. 55,998
Attorney/Agent for Applicants
c/o MINTZ, LEVIN
Tel: (617) 542-6000
Fax: (617) 542-2241
Customer No. 30623